(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51147, Nov. 7, 1983]

§ 184.1979 Whey.

(a)(1) *Whey*. Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1*N* hydrochloric acid per 100 grams. The acidity of whey, sweet or acid, may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(2) *Concentrated whey*. Concentrated whey is the liquid substance obtained by the partial removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(3) *Dry or dried whey*. Dry or dried whey is the dry substance obtained by the removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(b) The ingredients meet the following specifications:

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled ''Total Nitrogen—Official Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solids.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10

parts per million (0.001 percent) as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(3) The whey must be derived from milk that has been pasteurized, or the whey and modified whey product must be subjected to pasteurization techniques or its equivalent before use in food.

(c) Whey, concentrated whey, and dry (dried) whey may be used in food in accordance with good manufacturing practice as indicated in §184.1(b)(1).

(d) The label on the whey form sold to food manufacturers shall read as follows:

(1) For whey: ''(Sweet or acid) whey'' or ''whey (____% titratable acidity).

(2) For concentrated whey: ''Concentrated (sweet or acid) whey, ____% solids'' or ''Concentrated whey (____% titratable acidity), ____% solids''.

(3) For dry (dried) whey: ''Dry (dried) (sweet or acid) whey'' or ''dry (dried) whey, (____% titratable acidity)''.

(e) Whey, concentrated whey, or dry (dried) whey in a finished food product shall be listed as ''whey.''

[46 FR 44439, Sept. 4, 1981; 47 FR 7410, Feb. 19, 1982, as amended at 54 FR 24899, June 12, 1989; 64 FR 1760, Jan. 12, 1999]

§ 184.1979a Reduced lactose whey.

(a) Reduced lactose whey is the substance obtained by the removal of lactose from whey. The lactose content of the finished dry product shall not exceed 60 percent. Removal of the lactose is accomplished by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced lactose whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced lactose whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The reduced lactose whey meets the following specifications:

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) Protein content, 16 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled ''Total Nitrogen—Official Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, 11 to 27 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, not more than 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane–Eynon General Volumetric Method'' under the